Human Research Protection Training Required for Research Personnel

The principal investigator, other investigators, or any other personnel who are to be engaged in human research (i.e., research personnel) for a study under VDSS IRB review will be required to have completed a valid human research protection (HRP) training before a study may be approved. After study approval and before study completion, it is the responsibility of the study's Principal Investigator to ensure that all research personnel maintain valid HRP training.

The policy goes into effect on July 1, 2023. This applies to new and ongoing studies that submit a request to the VDSS IRB for an expedited, full board, or continuing review on or after July 1, 2023.

Policy Rationale

To facilitate the ethical conduct of human research that follows applicable human research regulations, all researchers engaged in human research studies under VDSS IRB review should be expected to have current (i.e., not expired) human research protection training. This proposal reinforces criterion #7 of *Criteria for IRB Approval of Research* within the **Instructional Review Board: Guidance Summary** (p. 3):

> 7. Whether individuals proposing to supervise or conduct the research are competent and
>
> qualified

While there are no federal or state regulations that pertain to human research protection education or training requirements (see Appendix – Section A), several federal agencies have training mandates for all research personnel engaged in human research that is funded or authorized by the agency (e.g., National Institutes of Health (NIH), Veterans Health Administration (VHA)).

In addition, it is common for Institutional Review Boards, within Virginia and nationally, to require all research personnel engaged in human research to have current (i.e., not expired) human research protection training and to provide proof of this training (for examples, see Appendix - Section B).

VDSS Office of Research and Planning (ORP) has an annual subscription to the Collaborative Institutional Training Initiative (CITI) Human Subjects Protection training platform. If research personnel do not have access to sufficient HRP training at their home institution, ORP can provide access to the required CITI training courses at no cost.

Implementing New Standard Operating Procedures

To fulfill this new HRP training requirement, the VDSS IRB would require that all research personnel associated with a study under VDSS IRB review provide evidence of current HRP training before study approval may be granted. Research personnel is defined as institutional staff and contractors engaged in the study in question who will interact with human participants and/or the participants' identifiable data. This includes but is not restricted to: the principal investigator, co-investigator(s), faculty advisory (for

student researchers), study coordinator, and biostatistician. Please consult with the IRB if you have questions about to whom the training requirement applies.

Prior to study approval by the VDSS IRB, the Principal Investigator must submit documentation of current HRP training for all research personnel. The HRP training may be from either the CITI Training courses recommended by the VDSS IRB or an alternative human research protection training program from another organization that the VDSS IRB deems to be an equivalent level of training.[1] The HRP training certificate must be within its expiration date.[2] If the VDSS IRB determines that the human research protection training required from a research member's home institution is insufficient, CITI training access may be provided through ORP's CITI Training subscription at no cost to the researcher.

After a study is approved via an expedited or full review procedure, and before the study is completed, it is the Principal Investigator's responsibility to ensure all research personnel's training has not lapsed or expired. During the course of the study, the IRB may ask the Principal Investigator to send documentation that current research personnel's training status is updated. If new research personnel are added after IRB approval of the study, it is the Principal Investigator's responsibility to inform the IRB of any staff changes and provide documentation of that person's HRP training.

Changes to Protocol Submission Procedures:

- The Principal Investigator is required to submit the *Research Personnel* form as a separate attachment during the IRB review application process. The *Research Personnel* form is located on the VDSS IRB web page, under the Forms section.
- The *Request for Initial Review* form references the new *Research Personnel* form. The Request for Initial Review form will continue to ask for information on the types of human research subjects training completed by the Principal Investigator (PI) and their research staff. The PI is also asked whether s/he has more than one year of human subject research experience. See Figure on the next page.
- The Principal Investigator and co-investigators are required to submit their current *Curriculum Vitae* (CV) as part of the study submission process. No other research personnel involved in the study is required to submit their CV.

[1] At a minimum, the HRP training must contain curriculum on the following topics: defining human research subjects; Belmont Principles; federal regulations, including the Revised Common Rule (2018 requirements); risks to subjects and assessing risk; vulnerable populations and additional protections; informed consent (requirements, considerations, and waiver of documentation); subject privacy and data confidentiality; researcher conflicts of interest; IRB review processes; and unanticipated problems and reporting requirements. Student researchers may be required to document participation in responsible conduct of research education.

[2] If the training does not have an expiration date, the training should have been completed within three years of the IRB submission.

Figure 1. Request for Initial Review Form – Training and Experience Section

Training and Experience

Indicate the types of human research protection (HRP) training that you and your research staff have had during the most recent three years. Select all that apply.

☐ Collaborative Institutional Training Initiative (CITI) ☐ OHRP Training Modules

☐ SOCRA Clinical Research Professional (CRP) ☐ Local Institution's Training

☐ Investigator Meeting(s) ☐ Other HPR training (specify): Click or tap here to enter text.

☐ None, identify study personnel not trained Click or tap here to enter text.

Does the PI have more than one year of human subject research experience? ☐ Yes ☐ No

Complete and submit the *Research Personnel* form. Refer to the *Human Research Protection Training Required for Research Personnel* policy.

- *Studies Under IRB Review:* The PI should provide documentation (e.g., training completion certificate) of each research personnel's HRP training record during the study application process. The PI may request access to CITI training for themselves or their research personnel, which ORP will provide at no cost. The PI must submit proof of HRP training completion (e.g., certificate of completion) for each research personnel listed on the *Research Personnel* form.
- *New Research Personnel Added After Study Approved via Expedited or Full Review:* After IRB approval of a study, changes to the status of non-PI research personnel (personnel attrition or additions), or any research personnel training fulfillment notifications to the VDSS IRB, are not considered a modification to an approved study (i.e., a Modification to Approved Study form submission is not necessary). However, the PI is expected to submit an updated *Research Personnel* form to the IRB when new research personnel are added to the study after study approval. In addition, each research personnel's proof of HRP training must be submitted to the VDSS IRB, or the PI should request access to ORP's CITI training courses. If access to ORP's CITI training courses is requested, once the research personnel has successfully completed the necessary HRP training course, the PI must submit the research personnel's CITI Program Completion Certificate to the VDSS IRB.
- *Research Personnel HRP Training Is About to Expire After Study Approval and Prior to Study Completion:* It is the responsibility of a study's PI to ensure that all research personnel's HRP training is current and up-to-date after study approval has been granted and for the duration of the study. If the training certification will expire during this time, the personnel must renew their training and the PI must provide evidence that the HRP training is current once again. The PI is required to re-submit the Research Personnel form when new or refresher training has been completed.

Human Research Protection Training Requirement Fulfillment

The VDSS IRB will accept documentation of successful completion of HRP training from the following programs:

Organization	Training Courses
Collaborative Institutional Training Initiative (CITI) Program	• No prior CITI training: Human Subject Research (HSR) Basic Course • Prior CITI training Recertification: HSR Basic Course or HSR Refresher Course

Completion of HRP training from other organizations may also fulfill VDSS IRB's HRP training requirement. This determination will be made by the VDSS IRB Chair or Administrator on a case-by-case basis. See Footnote #1 on page 2.

APPENDIX

A. Applicable Federal or State Regulations

There are no applicable federal or state regulations that pertain to training or educational requirements for the researchers who are conducting human research. However, some federal agencies have training mandates for all research personnel engaged in human research funded by their organization. For example, the National Institutes of Health (NIH) has a human subjects protection education requirement for all investigators and key personnel involved in NIH-funded human subjects research. This requirement can be fulfilled by completing training offered by the Office for Human Research Protections (OHRP).

B. Practices at Other Institutional Review Boards (IRBs)

Within Virginia and nationally, it is common for IRBs to have a policy that requires **all** research personnel added to IRB study submissions to have had recent training in human subject research protection. Below are some examples:

Virginia Commonwealth University:

> "All research personnel must officially be affiliated with VCU and have their CITI training from VCU. VCU will only accept CITI course credit that is linked to a VCU CITI account (basic and refresher courses). All research personnel must complete VCU's Human Subjects Protection basic course. Submissions of all types (initial, continuing review, etc.) will not receive IRB approval until research personnel CITI accounts are current."
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> Source: https://research.vcu.edu/training/citi-training

University of Virginia:

> "Personnel being added MUST have current training in human subject research protection training before they may be added. See the CITI Training website."
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> Source: https://research.virginia.edu/irb-hsr/responsibilities-principal-investigators

The **National Institutes of Health** (NIH) has the following applicable policy:

> "Policy: Beginning on October 1, 2000, the NIH will require education on the protection of human research participants for all investigators submitting NIH applications for grants or proposals for contracts or receiving new or non-competing awards for research involving human subjects…Before funds are awarded for competing applications or contract proposals involving human subjects, investigators must provide a description of education completed in the protection of human subjects for each individual identified as "key personnel" in the proposed research. Key personnel include all individuals responsible for the design and conduct of the study. The description of education will be submitted in a cover letter that accompanies the description of Other Support, IRB approval, and other information in accordance with Just-in-Time procedures."
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> Source: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html